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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,529	07/24/2000	PATRICIA KANNOUCHE	192863US0PCT	6934

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/05/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/05/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

09/555,529

Applicant(s)

KANNOUCHE ET AL.

Examiner

Diana B. Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-79 is/are pending in the application.
- 4a) Of the above claim(s) 43-58 and 66-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30,32-34,36-42,59,60,62,64,65 and 79 is/are rejected.
- 7) ☒ Claim(s) 31,35,61 and 63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the Amendment including a complying complete set of claims filed January 11, 2007. Claims 30-42, 59-65 and new claim 79 are now under consideration; claims 30, 32-34, 39-42, 59, and 64-65 have been amended. Claims 43-58 and 66-78 are withdrawn (see further explanation below); it is noted that withdrawn claims 51-53, 56-58, 74, and 76 have also been amended.

Election/Restrictions

2. Claims 43-58, 66-73, and 75-78 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Additionally, it is noted that applicant has amended claim 74 so as to delete SEQ ID NOS 18 and 19, which were elected in the reply of June 3, 2003. Accordingly, claim 74 is now also withdrawn from further consideration as being drawn to a nonelected invention. It is noted that new claim 79 recites elected SEQ ID NOS 18 and 19, and is therefore now under consideration.

Claim Objections

3. Claims 31, 35, 61 and 63 are objected to because of the following informalities: the claims depend from rejected base claims.

Claim Rejections - 35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 39-42 and 64-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 39-42 and 64-65 have been amended such that they are drawn to any human cell encompassing the molecules of the claims. While applicants' specification discloses bacteria and particular lines of human cells comprising vectors, plasmids and viral constructs that express various kin17 proteins and variants thereof, the specification as originally filed does not broadly disclose human cells comprising polynucleotides that encode such proteins, as encompassed by the instant claims. The claims as written are sufficiently broad so as to encompass any type of human cell comprising the claimed polynucleotides in any form (including polynucleotides which are [unlike the molecules exemplified in the specification] free of any type of vector, plasmid, or viral sequences). In the remarks of January 11, 2007, Applicant refers to pages 26, 28, and 31-33 as providing support for the amendments to the claims. However, these locations of the specification disclose specific cell lines containing particular plasmid, vector and viral constructs; this disclosure of a limited number of cell lines is not equivalent to and does not constitute a disclosure of the broad subject matter now claimed. Accordingly, applicants' amendments introduce new matter.

6. Claim 79 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

It is noted that the Remarks of January 11, 2007 state that new claim 79 "finds support in original Claim 74." However, claim 74 was not an original claim. Further, while the originally filed specification does provide basis for a polynucleotide consisting of SEQ ID NO: 18 and a polynucleotide consisting of SEQ ID NO: 19 (see, e.g., page 5 of the specification), the instant claim is drawn to an isolated polynucleotide "which consists of at least one of SEQ ID NO:18 and SEQ ID NO:19" (i.e., the claim encompasses a polynucleotide that consists of SEQ ID Nos 18 and 19 contiguous with one another, in either orientation, within a single polynucleotide). As such polynucleotides were not disclosed in the application as originally filed, applicants' amendment introduces new matter.

Claim Rejections - 35 USC § 112, second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 30, 32-34, 36-38, 40-42, 59-60, 62, and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30, 32-34, 36-38, 40-42, 59-60, 62, and 64 are indefinite over the recitation of the language "nucleotide sequence which encodes a human (claim 30 and dependent claims)/mouse (claim 59 and dependent claims) kin17 protein which

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comprises an amino acid sequence in SEQ ID NO: ___ with the exception that amino acids ___ to ___ are deleted in SEQ ID NO: ____.” It is noted that the language “nucleotide sequence which encodes a _____ kin17 protein which comprises the amino acid sequence in SEQ ID NO: ___ with the exception that amino acids ___ to ___ are deleted in said SEQ ID NO: ____” is clear and definite, in that this language clearly refers to a single, particular sequence and clearly describes how that particular sequence differs with regard to the recited SEQ ID NO. However, the recitation “an amino acid sequence in...” renders the scope of the claims unclear. The language “an amino acid sequence in” suggests that the claims may encompass other amino acid sequences within the construct of “SEQ ID NO: ___ with the exception that amino acids ___ to ___ are deleted in SEQ ID NO: ____” that might be considered to encode a “human kin17 protein” (claims 30 and dependent claims) or a “mouse kin17 protein” (claim 59 and dependent claims). It is not clear what portions/subsequences of the recited molecules would meet this limitation, how the recitation of the SEQ ID NO actually limits the claims, and how the recited deletion region actually limits the claims with regard to such embodiments. For example, to the extent that the claims encompass molecules encoding kin17 proteins that do not comprise “the” full length “amino acid sequence in SEQ ID NO: ___ with the exception that amino acids ___ to ___ are deleted in said SEQ ID NO: ____,” how would one of skill in the art identify such molecules in the absence of the particular sequence “SEQ ID NO: ___ with the exception that amino acids ___ to ___ are deleted in said SEQ ID NO: ____?” Thus, the metes and bounds of the claims are unclear.

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The comments of Applicants' representative with regard to the definiteness of the language "with the exception that amino acids ____ to ____ are deleted in SEQ ID NO: ____" in the Remarks of January 11, 2007 are noted (see page 11). However, the claim language remains indefinite as a result of the use of the recitation "an amino acid sequence" rather than "the amino acid sequence." This rejection could be overcome by amending the claims to employ the definite claim language noted above.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 79 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuda et al (The Journal of Biological Chemistry 268(33):24950-24958 [1993]) in view of

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Sambrook et al (Molecular Cloning: a Laboratory Manual, 2nd edition, Cold Spring Harbor Laboratory Press 1989, page 11.4).

Matsuda et al disclose double-stranded vectors comprising instant SEQ ID NO: 18 (see entire reference, particularly the "Materials and Methods" section at pages 24950 and Figure 3, particularly nucleotides -270 through -249, which are the reverse complement of instant SEQ ID NO: 18). Matsuda et al do not disclose a polynucleotide that consists of SEQ ID NO: 18. Sambrook et al teach that oligonucleotide probes 19-40 nucleotides in length that perfectly match their target sequence are useful in a variety of hybridization based assays, and that such probes, because of their "base composition and size," facilitate the specific detection and differentiation of a desired target sequence from "closely related sequences that are not perfectly matched" (see entire reference). In view of the teachings of Sambrook et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have to have prepared any oligonucleotide 19-40 nucleotides in length that perfectly complemented the sequence of Matsuda et al, including an oligonucleotide consisting of instant SEQ ID NO: 18. An ordinary artisan would have been motivated to have prepared any such oligonucleotide to facilitate the specific detection of the target molecule taught by Matsuda et al and the differentiation of that molecule from closely related molecules, as suggested by Sambrook et al.

12. Claim 79 is rejected under 35 U.S.C. 103(a) as being unpatentable over EST database accession no. A1089251 (NCI-CGAP; gb09a11.x1 Soares pregnant uterus NbHPU Homo sapiens cDNA clone, 8/1998) in view of Sambrook et al (Molecular

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Cloning: a Laboratory Manual, 2nd edition, Cold Spring Harbor Laboratory Press 1989, page 11.4).

EST database accession no. AI089251 discloses a (double stranded) cDNA clone comprising instant SEQ ID NO : 19 (see entire reference, particularly nucleotides 218-243 of the sequence). The EST database entry does not disclose a polynucleotide that consists of SEQ ID NO: 19. Sambrook et al teach that oligonucleotide probes 19-40 nucleotides in length that perfectly match their target sequence are useful in a variety of hybridization based assays, and that such probes, because of their "base composition and size," facilitate the specific detection and differentiation of a desired target sequence from "closely related sequences that are not perfectly matched" (see entire reference). In view of the teachings of Sambrook et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have to have prepared any oligonucleotide 19-40 nucleotides in length that perfectly complemented the sequence of the EST database, including an oligonucleotide consisting of instant SEQ ID NO: 19. An ordinary artisan would have been motivated to have prepared any such oligonucleotide to facilitate the specific detection of the target molecule taught by the EST database and the differentiation of that molecule from closely related molecules, as suggested by Sambrook et al.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is

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571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Diana B. Johannsen
Primary Examiner
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